Design for the Environment Formulator Program: *A Discriminating and Protective Approach to Cleaning Product Review and Recognition*

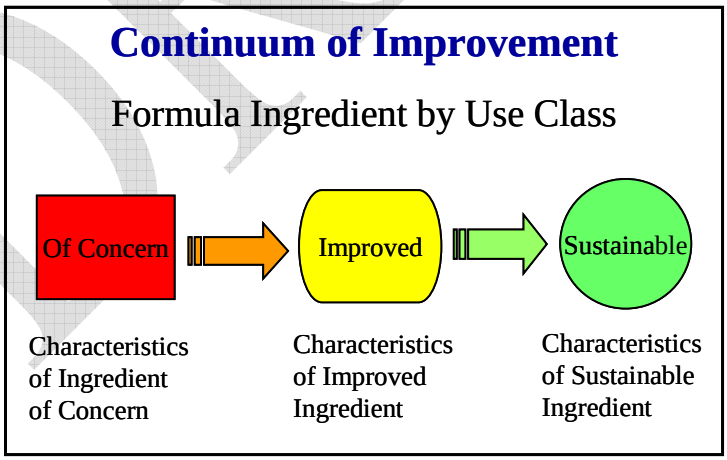
July 2006

Situated in the U.S. EPA's Office of Pollution Prevention and Toxics (OPPT), the Design for the Environment (DfE) Formulator Program is a product formulator's gateway to OPPT's unique chemical expertise, information resources, and guidance on greener chemistry. The program gathers hazard information on chemical ingredients and works with OPPT's science experts to assess this information and compare the relative safety of chemicals.

Since 1997, DfE has offered recognition to those companies who design for the environment and human health by only using safer chemicals. To date more than 160 chemical products have been recognized by the program. A complete list of partner companies and products can be found at: http://www.epa.gov/dfe/pubs/projects/formulat/formpart.htm.

What Makes DfE Formulator Review Unique? The DfE Program is distinct from all other product recognition or ecolabeling programs because of two defining characteristics: its assessment methodology and its technical review team. The DfE technical review team has many years of experience and is highly skilled at assessing chemical hazards, applying predictive tools, and identifying safer substitutes for chemicals of concern.

The review team applies the DfE assessment methodology by carefully reviewing each product component[1], starting with the chemical component's structure, to determine its key health and environmental characteristics. (The review includes all chemicals, including those in proprietary raw material blends, which manufacturers share with DfE in confidentiality). The review team then compares an ingredient's characteristics to other chemicals in the same use class, considers possible negative synergies between ingredients, and places the ingredient on a continuum of improvement relative to other similar chemicals.



Through its review team and methodology, DfE provides information to formulators that helps them select from among the safest chemicals in an ingredient class. The approach is adaptable

[1] A *component* is a chemical as identified by its Chemical Abstract Service (CAS) number. An *ingredient* may be one component or a blend of multiple components.

to changing circumstances and new information, emphasizing continuous improvement as the opportunities for safer formulations grow with chemical innovation.

How Does DfE's Component-Based Review Compare with Other Product-Based Approaches? The following examples showcase some of the key benefits of DfE's component-based review and the extra measure of protection it often provides:

DfE uncovers chemicals of concern that can be masked by raw material blends or by dilution in water. By focusing at the component level and on key inherent characteristics, DfE is able to carefully scrutinize formulations and make meaningful calls on potential concerns. For example, a surfactant that is acutely toxic to aquatic organisms and environmentally persistent can appear to pose a low concern when blended with other less toxic and less persistent surfactants. Similarly, water, typically the largest percentage ingredient even in concentrates, can mask the effects of a hazardous chemical.

DfE spots negative synergies between product components. These potentially dangerous chemical combinations, which occur with surprising frequency in cleaning products, pose concerns for both acute and longer-term effects. For example, oxidizing agents, like hydrogen peroxide, can release the sensitizing potential of certain citrus fragrances; another example, mixing nitrogen-containing compounds with amines will create nitrosamines, potent carcinogens.

DfE uses its expert knowledge and predictive tools to supplement lists of chemicals of concern. Few chemicals in commerce have been adequately tested, esp. for chronic effects, like cancer and developmental toxicity and thus lists of chemicals with these effects are partial at best. DfE uses its knowledge of the structural similarities between chemicals and its predictive models to flag product components with similar potential effects.

DfE screens all fragrances and dyes for chemicals that may pose serious health or environmental effects. Some of the chemicals of most potential concern in cleaning products are those in fragrances and dyes. Chemical ingredients in these classes include sensitizers, carcinogens, and environmentally toxic and persistent compounds. Small quantities don't necessarily mean small hazards: A person, once sensitized to a chemical, can have an allergic response even if exposed at minute levels.

DfE recommends safer substitutes for chemicals of concern. Sustainability requires innovation and continuous improvement. The DfE program works directly with EPA's Green Chemistry specialists to identify and recommend safer chemicals to its formulator partners, continuously raising the bar and redefining the meaning of environmentally preferable products.

The following matrix highlights many of the endpoints reviewed by the DfE Formulator Program team. The matrix should help purchasing entities and others understand what DfE considers in its review, what its recognition means, and how they should view products that carry the DfE logo.

Category	EPA Design for the Environment	Comments
Origins	Chemical review and analysis based on EPA New Chemicals Program, which has reviewed more than 30,000 chemicals since 1977 (pursuant to the Toxic Substances Control Act). EPA technical experts consider multiple factors in reviews, including predictive models and chemical analogs, and make educated judgments. Since most chemicals lack a complete health and environmental profile, expert judgment is critical to the accurate characterization of potential hazards.	
Product Performance Testing	To ensure a baseline measure of performance, DfE will begin requiring all current and future partners to demonstrate that their products perform effectively. This can be done by submitting appropriate test results as specified in Annex I or by providing equivalent performance tests agreed upon by DfE.	Formulator Company's Comments: Independent product performance testing is intended to increase consumer confidence, establish non-bias benchmark standards and to improve products. However, the laboratory bench tests tend to be non-representative of "real world" variables, encourage a "beat the test" mentality and can discourage innovation, particularly in the safety and environmental arena. When used, such testing should not be viewed as absolute but as a general guide.
Quality Assurance/Control	The Memorandum of Understanding between EPA/DfE and the partner company affirms that those ingredients disclosed to EPA during the product review process are in fact the only ingredients intentionally added or known to be present. EPA is currently exploring additional methods for ensuring further quality control.	

Category	EPA Design for the Environment	Comments
(Acute) Oral toxicity (LD_{50}) and inhalation toxicity (LC_{50})	DfE follows the UN's Globally Harmonized System for rating oral and inhalation toxicity. No *components* classified under "Danger" are found in DfE-recognized products. At a minimum, each *component* has an*:* 1) Acute oral toxicity LD_{50} > 300mg/kg, and 2) Acute Inhalation toxicity LC_{50} >10 mg/L. For components without data, DfE relies on the judgment of its technical experts to identify chemicals that, by analogy, pose a potential acute oral or inhalation toxicity hazard.	
Acute Dermal Toxicity (LD_{50})	When data are available, DfE follows the UN's Globally Harmonized System for rating acute dermal toxicity. No *components* classified under "Danger" are found in DfE-recognized products. At a minimum, each *component* has an*:* 1) Acute dermal toxicity LD_{50} > 1000 mg/kg. For components without data, DfE relies on the judgment of its technical experts to identify chemicals that, by analogy, pose a potential acute dermal toxicity hazard.	
No Carcinogens and Reproductive Toxins	DfE reviews cancer concerns through: 1) Published cancer studies, 2) Potential synergistic effects between components that may produce carcinogenic byproducts (e.g. nitrites and amines form nitrosamines), 3) EPA's ONCOLOGIC model, and 4) EPA's expert judgment. In addition, DfE supplements its reviews with the following lists: 1) IARC, 2) NTP, 3) U.S. EPA, and 4) OSHA. DfE reviews reproductive toxicity concerns though: 1) Published studies on reproductive toxicity, and 2) EPA's expert judgment. In addition, DfE supplements its reviews with the following lists: 1) California's Proposition 65 – Safe Drinking Water and Toxic Enforcement Act of 1986.	Few chemicals in commerce have been sufficiently tested to determine their potential for human carcinogenicity. In the absence of testing, EPA's ONCOLOGIC model and expert judgment help fill data gaps. The referenced lists cover only those chemicals which have been fully evaluated by the agencies. It is likely that other carcinogenic, mutagenic, and reproductively toxic (CMR) chemicals have not yet been identified. Similarly, lists of reproductive toxins are limited by lack of scientific studies and comprehensive agency assessments.

Category	EPA Design for the Environment	Comments
Mutagenicity	Depending on component class and certainty of effect, DfE limits *components* that are potential mutagens. Potential concerns for mutagenicity are identified through published studies, internal EPA databases, and comparison to chemical analogs. DfE often looks at multiple mutagenicity test results, and exercises expert judgment in interpreting and characterizing the potential hazard.	
Other Chronic Health Effects _____ Basic Internal Organ Effects (Including Endocrine System & Blood) _____ Central Nervous System (CNS) Effects	Depending on component class, certainty of effect, and percentage in formulation, DfE limits *components* that may pose other potential chronic health or internal organ effects. Potential concerns for chronic health effects are identified through published studies, internal EPA databases, and comparison to chemical analogs.	
Skin and Eye Irritation	To minimize potential for dermal and eye irritation or injury, product pH should be ≥ 2 and ≤ 11.5. Depending on percentage in the formulation, DfE limits *components* that are suspected or known severe skin and eye irritants.	Most cleaning products have ingredients, like surfactants, that are expected skin and eye irritants, especially at concentrated levels. OSHA requires product-level irritation information on all MSDSs, if any positive results are available.
Skin Sensitization	Depending on component class, certainty of effect, and percentage in the formulation, DfE limits *components* that are suspected or known skin sensitizers. DfE reviews product formulations for negative synergistic effects between *components* (e.g. byproducts of limonene and oxidizing agents).	Sensitization potential often depends on component class and chemical synergies. OSHA requires product-level sensitization information on all MSDSs, if any positive results are available.
Respiratory Sensitization	A *component's* potential for respiratory sensitization is reviewed in conjunction with the chemical's other attributes. Depending upon certainty of effect, component class, and percentage in the formulation, DfE limits *components* that may cause respiratory sensitization.	DfE is able to consider multiple factors in its review, and make educated judgments because of the diverse expertise of its technical workgroup. Since most chemicals lack a complete health and environmental profile, expert judgment is critical to the accurate characterization of potential hazards.

Category	EPA Design for the Environment	Comments
Combustibility	DfE takes note of *product* flashpoint as appropriate and seeks to ensure low concerns for combustibility.	Flashpoint is generally not a concern when dealing with water-based mixtures. Flammable liquids are regulated by: ➢ 49CFR173.120 (a) (5) - Flammable Liquid Definition ➢ 49CFR173.150 (e) Aqueous Solutions of Alcohol ➢ 40CFR261.21 (a) (1) Characteristic of Ignitability
Photochemical Smog, Tropospheric Ozone Production, and Indoor Air Quality	DfE seeks to minimize VOCs and restricts components that are also Hazardous Air Pollutants (HAPs) or are on EPA's Toxics Release Inventory (TRI) DfE strives to optimize the health and environmental preferability of products. The lowest possible VOC-level may not correspond to the safest formulation.	
(Acute) Toxicity to Aquatic Life	Acute aquatic toxicity for a *component* is evaluated in conjunction with the chemical's other attributes; focus is on the key distinguishing characteristics that make one chemical safer than another. For example, all high-functioning surfactants have high aquatic toxicity (low LC_{50} values). Safer surfactants are those that are readily biodegradable and do not degrade to chemicals that are persistent or toxic.	
Chronic Toxicity to Aquatic Life	DfE considers data if available or estimation models, and in particular limits those *components* whose aquatic toxicity increases through long-term (chronic) exposure.	
Aquatic Biodegradability	DfE evaluates biodegradation for all *components* in conjunction with a chemical's other attributes; focus is on the key characteristics that make one chemical safer than another. For ingredients, like surfactants, where rate of biodegradation is key to safer chemistry, a DfE-recognizable chemical must be readily biodegradable and, very importantly, its degradation products must be of low concern.	
Bioaccumulation	DfE uses data, models, and EPA's expert judgment to assess a *component's* potential to bioaccumulate. Bioaccumulation potential is reviewed in conjunction with a chemical's other attributes. Depending upon certainty of effect, component class, and percentage in the formulation, DfE limits components that may bioaccumulate.	

Category	EPA Design for the Environment	Comments
Eutrophication	No inorganic phosphates (known to be present or intentionally added) allowed, because of their potential for eutrophication.	Algal blooms possible at concentrations of less than 200 parts per billion (about 0.000002%) in 96 hours (certain inorganic phosphates have produced exponential growth of green algae at levels as low as 50 parts per billion).
Packaging	DfE encourages the use of environmentally friendlier packaging, but does not require specific types of packaging.	
Concentrates	DfE reviews all *chemicals* in a formulation, without regard to the product dilution.	
Fragrances	DfE works directly with fragrance houses to improve their formulations. C*omponents* are screened for: 1) Sensitization, 2) Carcinogenicity, 3) Mutagenicity, 4) Reproductive toxicity, 5) Environmental persistence, 6) Aquatic toxicity, and 7) Other hazardous characteristics.	Following IFRA's Code of Practice may not be sufficiently protective when a fragrance is added to a cleaning product. The sensitization potential of terpenes (considered both fragrances and solvents) can be released when combined with oxidizers, such as hydrogen peroxide.
Prohibited Ingredients: Alkylphenol ethoxylates (APEs)	Not acceptable in DfE-recognized products. APEs, like all surfactants, are compared based on their key distinguishing characteristics: 1) Rate of biodegradation, 2) Aquatic toxicity, and 3) Degradation products. APEs do not have acceptable profiles because they degrade to products that are increasingly toxic and are potential endocrine mimics.	DfE has identified surfactants that are safer than APEs, and have comparable performance and price. In the context of its product reviews, DfE provides this information on safer substitutes to its formulator partners.
Prohibited Ingredients: Dibutyl phthalate	This and other phthalates of concern are not acceptable in DfE-recognized products based on key characteristics for plasticizers.	Dibutyl phthalate, a plasticizer, can also be found in fragrances.
Prohibited Ingredients: Heavy metals	Not acceptable in DfE-recognized products.	
Prohibited Ingredients: Ozone-depleting compounds	Not acceptable in DfE-recognized products.	The Montreal Protocol (1987) initiated the phase-out of HCFCs and banned almost all CFCs, including those used as propellants in cleaning products.
Prohibited Ingredients: Optical brighteners	Reviewed based on key characteristics: potential developmental/reproductive effects, especially human toxicity, aquatic toxicity, and persistence. Because of low concern for those characteristics, many optical brighteners have acceptable profiles.	
Training	Memorandum of Understanding requires each partner company to provide its customers with information on environmental and worker safety matters.	OSHA, DOT, and other authorities require manufacturers to provide handling and other worker safety information.

Category	EPA Design for the Environment	Comments
Animal Testing	DfE encourages the use of non-animal test methods, as available. DfE supplements data with predictive models, literature reviews, internal data sources, and the judgment of EPA's technical experts.	
Labeling Requirements	Memorandum of Understanding requires each partner company to provide its customers with information on environmental and worker safety matters.	OSHA, DOT, and other authorities require manufacturers to provide handling and other worker safety information.

Annex I: Product Performance Testing under EPA's Design for the Environment Formulator Program

DfE believes performance testing requirements should be product category specific, and will accept any valid and scientifically sound method of demonstrating product performance. Examples of performance requirements that are acceptable to DfE include but are not limited to:

Glass Cleaners – Meets user requirements for cleaning, streaking and smearing when tested according to CSPA method DCC09 or equivalent method agreed upon by EPA DfE.

General Purpose Cleaners – Meets user requirements for soil removal on relevant substrates when tested according to ASTM method D4488-95 or equivalent method agreed upon by EPA DfE.

Carpet Cleaners – Perform equal to or better than nationally recognized carpet cleaners in the same category using CSMA DCC-03 and AATCC Test Method 171-1995 or equivalent method agreed upon by EPA DfE.

Washroom Cleaners – Meets user requirements for soil removal using ASTM D5345 or equivalent method agreed upon by EPA DfE.